IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
Foster *et al.*
Appl. No. 09/937,484
§ 371 Date: January 23, 2002
For: **Use of a Lectin or Conjugates for Modulation of C-Fibre Activity**

Confirmation No. 2134
Art Unit: 1654
Examiner: Audet, Maury A.
Atty. Docket: 1581.0870000/RWE

Amendment and Reply To Restriction Requirement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Mail Stop Non-Fee Amendment

Sir:

In reply to the Office Action dated October 3, 2003 (PTO Prosecution File Wrapper Paper No. 9), Applicants submit the following Amendment and Remarks. This Amendment is provided in the following format:

(A) Each section begins on a separate sheet;

(B) Starting on a separate sheet, amendments to the specification by presenting replacement paragraphs marked up to show changes made;

(C) Starting on a separate sheet, a complete listing of all of the claims:

- in ascending order;
- with status identifiers; and
- with markings in the currently amended claims;

(D) Starting on a separate sheet, the Remarks.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying

this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

30. (Original) A conjugate comprising a first lectin coupled to a peptide or protein, wherein said first lectin is non-endogenous to humans, and wherein said peptide or protein is substantially free of Clostridial neurotoxin enzyme activity.

31. (Original) A conjugate according to Claim 30 wherein the peptide or protein is a second lectin.

32. (Original) A conjugate according to Claim 30 wherein the first lectin binds to a galactosyl residue.

33. (Original) A conjugate according to Claim 30 wherein the first lectin binds to a glucosyl residue.

34. (Original) A conjugate according to Claim 31 wherein the first and second lectins are different.

35. (Original) A conjugate according to Claim 34 wherein the first lectin binds to a galactosyl residue and the second lectin binds to a glucosyl residue.

36. (Original) A conjugate according to Claim 30, wherein the peptide or protein is an endopeptidase, or a Clostridial neurotoxin substantially free of enzyme activity.

37. (Original) A conjugate according to Claim 30, wherein the first lectin is a lectin derivative, said derivative having been modified to remove a carbohydrate group while maintaining the ability of the derivative to bind C-fibres.

38. (Original) A nucleic acid sequence encoding the conjugate of Claim 30.

39. (Currently amended) A method of treating a disease or condition resulting from an inhibition or stimulation of C-fibre neuron activity, by modulating C-fibre activity, comprising administering an effective amount of a lectin, or a nucleic acid sequence coding said lectin, or a conjugate according to Claim 30, or a nucleic acid sequence according to Claim 38, to a patient.

40. (Original) A method according to Claim 39 for inhibiting C-fibre activity.

41. (Original) A method according to Claim 39 for stimulating C-fibre activity.

42. (Original) A method according to Claim 39 wherein said disease or condition is selected from the group consisting of pain, psoriasis, inflammation and mucus hypersecretion.

43. (Original) A method of preparing a conjugate according to Claim 30, comprising coupling together, optionally via a linker, the first lectin and the peptide or protein.

44. (Original) A method of preparing a conjugate according to Claim 30, comprising expressing in a host cell a nucleic acid sequence according to Claim 38, optionally including a linker nucleic acid sequence located within said nucleic acid sequence provides a linker molecule between the first lectin and the peptide or protein of the conjugate.

45. (Original) A composition comprising a lectin and a peptide or protein, wherein the peptide or protein is an endopeptidase or a Clostridial neurotoxin free of enzyme activity.

46. (Original) A composition according to Claim 45, wherein the peptide or protein is an LH_N fragment of a Clostridial neurotoxin.

47. (Original) A method of treating a disease or condition resulting from an inhibition or stimulation of C-fibre neuron activity, by modulating C-fibre activity, comprising administering a composition according to Claim 45 to a patient.

Remarks

Claims 30-47 are pending with claims 30 and 45 being the independent claims. Claim 39 is sought to be amended. Support for the amendment to claim 39 may be found on page 13, lines 9-14, of the present specification. No new matter has been added by way of this amendment.

Applicants hereby provisionally elect to prosecute the invention of Group II, represented by claims 39-42 and 47. Applicants also elect the specific conjugate comprising *Erythrina cristagalli* lectin linked to the peptide component inactive LH_S /A(-) of Example 17. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made ***with*** traverse.

Applicants assert that this Restriction Requirement based on lack of unity of invention is improper and must be withdrawn. U.S. Patent and Trademark Office regulations provide guidance to Examiners in regard to unity of invention:

> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories: . . .
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; . . . .

37 C.F.R. § 1.475(b)(2).

Furthermore, the Administrative Instructions Under the PCT provide:

> (c) **Independent and Dependent Claims.** Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of

claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

(i) *If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.* Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

Administrative Instructions Under the PCT, Annex B, Part 1 (emphasis added).

The following examples are also provided as guidance to Examiners:

Example 1

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X.

Example 17

Claim 1: Protein X.

Claim 2: DNA sequence encoding protein X.

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Id. at Part 2.

Here, claims 30 and 45 are the only independent claims and are each part of Group I. Because these claims are in the same group, it necessarily follows that all of their dependent claims have unity of invention and should be examined together. Hence, claims 30-47 possess unity of invention and must be examined together. Moreover, the claims that recite peptides/proteins and nucleic acid molecules coding therefor are related like claims 1 and 2 of Example 17 shown above. The remaining dependent claims are related like claims 2 and 3 of Example 1 provided above. Just as the claims in these examples possess unity of invention, Applicants' claims 30-47 possess unity of invention. Furthermore, the Restriction Requirement does not cite any art to support the allegation of lack of unity of invention. Thus, the Restriction Requirement is improper because unity of invention exists amongst the claims.

Moreover, Applicants note that the application was considered to have unity of invention during the international phase. Since a search and examination has already been carried out during the international phase, it would place absolutely no burden on the examiner to examine all of the present claims.

Finally, it is improper to require restriction of a single claim. See, *In re Weber*, 198 U.S.P.Q. 332 (CCPA 1978) and *In re Hass*, 198 USPQ 334 (CCPA 1978). These cases make it clear that 35 U.S.C. § 121 does not grant the PTO the authority to refuse to examine a claim that may read on separate inventions. Section 121 only applies to separate inventions claimed in different claims.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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